

Application No. 10/518,817
Amendment Dated December 1, 2005
Reply to Office Action of September 26, 2005

AstraZeneca Docket No. 100727-1P US

Remarks

Claims 1-2, 6, 9 and 10 have been amended. Claim 7 has been cancelled without prejudice. New claims 11-16 have been added. The support for the new claims can be found in the originally filed claims 1-6 and page 11, line 11 of the original specification. Claims 1-6 and 9-16 are now pending after entry of this amendment.

Claim Amendment

Claim 1 is amended to eliminating the wordings that were objected to in the Office Action. In addition, X being N was deleted in pursuant to the restrict requirement. Finally, an "or" was added to the Markush group of "A" to correct the grammatical error. No new matter has been added.

Claim 2 is amended to read as "A is H, NHR² or OR²..." to correct the inconsistency with claim 1. Applicants inadvertently mistake "A" as "X" in drafting this language. The error is obvious in view of the claim 1 languages and the vast numbers of examples in the specification. In addition, A being hydrogen is supported in the original claim 1. No matter has been added.

Claim 6 is amended pursuing the restriction requirement.

Claims 9 and 10 are amended to include the limitations of claim 7, which is now cancelled.

Election/Restrictions

Applicants hereby elect Group I of the invention, in which X of formula (I) is C-A with traverse. Relevant claims have been amended to cancel the non-elected subject matters.

35 U.S.C. §112, Second Paragraph Rejection

In the Office Action, claims 1-7, 9 and 10 were rejected under 35 U.S.C. 112, second paragraph. Applicants respectfully submit that the amendments to claim 1, 2, 6, 9 and 10 and cancellation of claim 7 should be able to overcome this rejection. Withdrawal of this rejection is respectfully requested.

35 U.S.C. §112, First Paragraph Rejections (1)

In the Office Action, claims 1-16 and 20-26 were rejected under 35 U.S.C. §112, first paragraph for not providing enablement for making solvate or hydrate. Applicants assume that "claims 1-16 and 20-26" was a typographical error because the highest number of claim

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of the instant application is "10" before the entry of the instant amendment. Applicants respectfully traverse the rejection assuming it was intended for the pending claims and respectfully submit that the deletion of "solvate" or "hydrate" from the pending claims should overcome this rejection. Withdrawal of this rejection is respectfully requested.

35 U.S.C. §112, First Paragraph Rejections (2)

In the Office Action, claims 1-5 and 10 were rejected under 35 U.S.C. §112, first paragraph for not providing enablement for treating any or all disease or disorders mediated by Cathepsin S and cysteine protease. Applicants respectfully traverse this rejection as far as it applies to the amended claims.

The claims at issue are now amended to eliminate the wording of treating any or all diseases or disorders mediated by Cathepsin S and cysteine protease. Applicants respectfully submit that there is nothing in the pending claims that are not enabled. The methods of administration are described in great detail on pages 7-8 of the original specification. Withdrawal of this rejection is thus respectfully requested.

35 U.S.C. §102 Rejection

In the Office Action, claim 7 was rejected under 35 U.S.C. 102(b) as being anticipated by Niedermann et al. (U.S. Pat. No. 5,759,956). Claim 7 is now cancelled and withdrawal of this rejection is respectfully requested.

35 U.S.C. §103 Rejection

In the Office Action, claims 1-5 and 7-10 were rejected under 35 U.S.C. 103(a) as being unpatentable over Altman et al. (WO 03/020278) (hereafter "Altman"). Applicants respectfully traverse this rejection for the following reasons.

First, Applicants assume the mentioning of "Wood et al" in the middle of page 15 of the Office Action is a typographical error. If it is otherwise, Applicants invite the Examiner to further identify the reference and/or provide a copy of the reference.

To make an obviousness rejection, the Examiner bears the initial burden of establishing the prima facie case. In re Piasecki, 223 U.S.P.Q. 785, 788 (Fed. Cir. 1984). To establish a prima facie case, the Examiner must satisfy three requirements. First, the prior art relied upon, coupled with the knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or to combine references. See Karsten Mfg. Corp. v. Cleveland Gulf Co., 242 F.3d 1376, 1385, 58 U.S.P.Q.2d 1286, 1293 (Fed. Cir. 2001).

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Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. In other words, a hindsight analysis is not allowed. See Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1209, 18 U.S.P.Q.2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art reference or combination of references must teach or suggest all the limitations of the claims. See In re Wilson, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970).

In this case, the Examiner has not carried the burden of setting forth a *prima facie* obviousness rejection because the Examiner has not identified the motivation to select R being OR4 or NR3R4 in prior art. In fact, if one skilled person in the art reading Altman as a whole, he or she would be motivated not to use R being OR4 or NR3R4 because the entire document contains numerous examples, yet all of them are directed toward R being H. Especially, Altman expressly states that the preferred compounds are compounds of formulas II, IIa and III (see Altman, middle of page 6, bottom of page 7 and middle of page 8), wherein the R is H. Therefore, Altman actually teaches away from the present invention as claimed in the pending claims.

In addition, to make a *prima facie* obviousness rejection, the proposed modification must have a reasonable expectation of success. Altman describes compounds that are useful as inhibitors of Cathepsin K. See the middle of page 13 of Altman. Even though Altman mentions other Cathepsin enzymes in its background section, reading the document as a whole, it is clearly that these compounds are directed towards Cathepsin K (only Cathepsin K assays are provided in the application, see pages 13-16 of Altman). In contrast, the present invention is directed towards compounds and uses thereof that are active towards Cathepsin S. (See page 29 of the present application). Therefore, a skilled person reading Altman would not expect that the compounds of Altman (or proposed modification thereof as suggested by the Examiner) would be active towards Cathepsin S. Therefore, the Examiner has not carried the burden to make a *prima facie* obviousness case for this additional reason.

For the above reasons, Applicants respectfully submit that the pending claims are patentable and withdrawal of the rejection is respectfully requested.

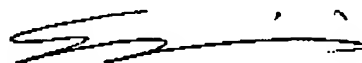
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Conclusion

Having responded all the objections and rejections, Applicants believe the pending claims are in condition for allowance and respectfully request a speedy Office Action so indicated.

Respectfully submitted,



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The Commissioner for Patents is hereby authorized to charge payment to Deposit Account No. 26-0166 for any fees associated with this communication.